UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,499	11/21/2001	Raman K. Bakshi	20385YDA	4343

210 7590 04/16/2007

MERCK AND CO., INC
P O BOX 2000
RAHWAY, NJ 07065-0907

EXAMINER	
SEAMAN, D MARGARET M	
ART UNIT	PAPER NUMBER
1625	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
1 MONTHS	04/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/990499
Filing Date: November 21, 2001
Appellant: Bakshi et al.
Appeal No. 2005-1793

REQUEST FOR REHEARING

It is respectfully requested that the decision by the Board of Patent Appeals and Interferences (Board) dated in the above-identified application (Ex parte Raman K. Bakshi et al., Appeal No. 2005-1793 (BPAI November 9, 2005) be reheard with an expanded panel on the written record as supplemented below.

The application was rejected under 35 U.S.C. 112, first paragraph, for lacking a fully enabling disclosure on March 11, 2002, which rejection was made final on August 9, 2002 and appealed on February 11, 2003. The issue was whether the disclosed substituted isoquinoline compounds of formula (I) supported a method reciting the use of a broader genus of compounds claimed solely by functional parameters. Finality was withdrawn and a requirement for an election of species was made on June 10, 2003, noting that the claimed invention was generic to a plurality of patentably distinct species. Applicant elected, with traverse, a single species as defined by Example 2 on page 75 of the specification. In the next action on the merits mailed August 26, 2003, there were no rejections made citing any prior art against the elected species and the generic claims were again rejected under 35 U.S.C. 112, first paragraph, for lacking a fully enabling disclosure. The generic claims were also rejected (albeit by using an incorrect form paragraph) under 35 U.S.C. 112, first paragraph, for failure to comply with the written

description requirements. These rejections were made final on December 2, 2003 and were subsequently appealed on April 12, 2004. The Examiner asserted that the disclosed substituted isoquinoline compounds of formula (I) did not enable or adequately describe methods claiming use of a broader genus of compounds identified solely by functional parameters. The merits panel reversed both of the rejections under 35 U.S.C. 112 first paragraph, stating that the relevant issue was whether the specification provided adequate written description and an enabling disclosure of a method which comprised administering the compound defined by Example 2 on page 75, the elected species. The merits panel concluded that once it has been determined that the elected species had been described and was enabled, then the Examiner could either allow any claim directed only to said species or move on to the next elected species and begin the examination process with respect to that species. The decision reversing the Examiner's rejection under 35 U.S.C. § 112, 1st paragraph for lack of enablement and written description is erroneous as a matter of law and fact in finding that the specification provided an adequate written description and enablement for the claimed invention.

PERIOD FOR REPLY

Appellant may file a reply to this request for rehearing within one (1) month of the mailing date of this request for rehearing. This one-month period may not be extended under the provisions of 37 C.F.R. § 1.136(a). After the expiration of this one-month period (plus an appropriate period for mail processing), the above-identified application will be forwarded to the Board for consideration of this request for rehearing.

ISSUE

Whether the Board erred in finding that the relevant issue in the appeal was whether the specification provided adequate written description and an enabling disclosure of a method which comprises administering the compound defined by Example 2 on page 75, the elected species, and in reversing the enablement and written description rejections of the generic claims.

SUMMARY OF ARGUMENT

The merits panel appears to have limited their consideration of the facts to the elected species and, in so doing, erred in their finding that the rejected claims were both adequately described and enabled. This finding, if allowed to stand, will result in the issuance of generic claims that do not recite the elected species but were evaluated only to the extent of the elected species of the compound set forth in Example 2 on page 75 of the specification. If the Examiner's rejections remain reversed, the application will be allowed and Applicants will be granted patent protection for broad claims without resolution of the issue as to whether the full scope of the claims has been adequately described or enabled by the specification.

ARGUMENT

The claims (39-75) were rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. Claims 39 and 74 (upon which all other claims stand or fall) are drawn to methods of treating erectile dysfunction in a male patient, comprising administering (orally in claim 74) an agonist of the MC-4R that may have selective binding properties for MC-4R, as set forth in claim 39. The specification indicates that an agonist of MC-4R is known and used to treat erectile dysfunction (MT-II, a synthetic cyclic heptapeptide, page 4 of the specification) but that this agonist is not selective only for MC-4R, i.e. it will also bind MC-1R, MC-2R, MC-3R and MC-5R, and as a result, undesirable side effects occur. Further, it must be administered parenterally, since it is not absorbed when administered orally. The specification indicates that it is desirable to use agonists selective for MC-4R in the treatment of erectile dysfunction to avoid these side effects and that it is desirable to have selective MC-4R agonists that could be orally administrable.

The claims describe the invention as compounds to be used in the treatment of erectile dysfunction, but these compounds are defined solely by functional limitations, i.e. selective binding properties and agonistic activity or agonistic activity and capability of oral administration. There are no structural limitations found in these claims. While the specification states that substituted isoquinoline compounds of formula (I) possess the claimed selective binding properties for MC-4R and are capable of oral administration, no structural or identifying characteristics of compounds other than those of formula (I) that possess the required function of being a selective,

orally administrable MC-4R agonist effective in treating erectile dysfunction are disclosed. Also it is clear that other structures do bind to the MC-4R receptor such as the cyclic heptapeptide discussed above, no guidance regarding what other structures would predictably share the required function of being a selective, orally administrable MC-4R agonist effective in treating erectile dysfunction is provided. Assays for determining if a compound binds to and activates MC-4R are provided as are assays for determining efficacy in penile reflex tests (pages 35, 37, 39, and 92 of the instant specification); however, per University of Rochester v. G.D. Searle & Co., 358 F.3d 916, 69 U.S.P.Q.2d 1886 (Fed. Cir. 2004), a screening assay, while providing a manner of identifying compounds that are selective MC-4R agonists, does not put one skilled in the art in possession of any compounds that are selective MC-4R agonists other than the disclosed compounds of formula (I). The claims (39-75) were also rejected under 35 U.S.C. 112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. For the same reasons as discussed supra, the claims of record are enabled for the administration of the substituted isoquinoline compound of formula (I), but are not enabled for the administration of unidentified compounds that are defined solely by functional limitations. As discussed above, there are no structural limitations, defining the encompassed compounds, set forth in the claims. The entire specification discusses solely the substituted isoquinoline compounds of formula (I) and no other compounds or structures are identified or discussed. No guidance regarding what other compounds or structures would predictably share the required function of being a selective, orally administrable MC-4R agonist effective in treating erectile dysfunction is provided. Up until the disclosure of the instant application, the art did not recognize any compounds that shared both selective binding and capability for oral administration. In the absence of such guidance, one who would practice the claimed invention would need to engage in an undue amount of trial-and-error experimentation without a reasonable expectation of success in order to practice the claimed invention with any other compounds than the substituted isoquinoline compounds of formula (I) to find selective, orally administrable MC-4R agonists and therefore, the specification does not enable one of skill in the art to make any other compounds than the substituted isoquinoline compounds of formula (I).

There are no art rejections against the elected species, there are no art rejections against any of the other disclosed species, and there are no art rejections over the full scope of the claims. There are no 35 U.S.C. 112, first paragraph rejections of record over the elected species of Example 2, nor are there any 35 U.S.C. 112, first

paragraph rejections of record over any of the other species of isoquinoline compounds of formula (I). Indeed, the Examiner explicitly stated that Applicants were in possession of and enabled for not only the particular species of Example 2 but also for all the species encompassed by formula (I). See page 4, paragraph 4 through page 5, paragraph 5 of the Examiner's Answer of June 22, 2004. It is further noted that the examiner issued claims drawn to the compounds chemically identical to the substituted isoquinoline compounds of formula (I) in the parent application. There are no (and have never been any) pending claims directed only to the elected species or to the substituted isoquinoline compounds of formula (I). The only inference that can be made from these facts is that the Examiner, upon finding no basis to reject the elected species, followed proper Office policy and examined the rest of the disclosed species, finding none of them unpatentable. The examiner then properly examined the generic claims for the full scope encompassed by the claims. This is appropriate and in accordance with MPEP 808.01(a). It is noted also that MPEP 806.01 indicates that the election of a single species where only generic claims are presented is considered provisional, dependent upon the results of the examination of the elected species. The merits panel erred in failing to take this procedure into consideration, as well as failing to consider the statements of the Examiner in order to come to the proper conclusion that the full scope of the claims had been examined. As a result, the merits panel failed to properly consider the full scope of the generic claims and the issue of whether that full scope meets the requirements of written description and enablement under 35 U.S.C. 112 first paragraph.

Finally, The merits panel stated on page 6 of the decision that

> "[o]nce it has been determined that the elected species has been described and enabled by the specification, the examiner can either (i) allow any pending or newly-submitted claims directed only to said species; or (ii) move on to the next elected species and begin the examination process with respect to that species."

Since there are no pending claims to the elected species and since the Examiner has examined the full scope of the claim, including the other disclosed species, the decision by the board, absent a favorable decision to this request for rehearing, places the examiner and the Office in the untenable position of having no other recourse than to allow claims of broader scope than adequately described and enabled.

CONCLUSION

For the reasons set forth above, it is respectfully submitted that the merits panel appears to have limited their consideration of the facts to the elected species and, in so doing, erred in their finding that the rejected claims were both adequately described and enabled. If the Board's decision is permitted to stand, the currently pending claims will be allowed in view of the absence of applicable prior art and the reversal of the rejections of record. However, without resolution of the issue as to whether the full scope of the claims has been adequately described or enabled by the specification, the record regarding the proper scope of invention encompassed by the claims will be unclear.

We respectfully request reconsideration of this decision by an expanded panel of the Board.

Respectfully submitted,

Margaret Seaman
Primary Examiner, Art Unit 1625

Approved:

George Elliott, Director
Technology Center 1600

John Love
Deputy Commissioner for
Patent Examination Policy